REMARKS

Status of the claims

Claims 7, 9, 11, and 12 are currently pending.

Claims 7, 9, 11, and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bryans et al., WO 99/21824 (Atty Ref. No. PC17322) in view of Beers et al., The *Merck Manual of Diagnosis and Therapy*, 17th Ed., pages 481-482 ("*Merck*"). Claims 7, 9, 11, and 12 stand provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of copending U.S. Patent Application No. 10/935,824 ("the '824 application"; Atty Ref. No. PC25972A) in view of Beers et al.; claim 2 of copending U.S. Patent Application No. 11/675,389 ("the '389 application"; Atty Ref. No. PC25026B) in view of Beers et al.; and claim 21 of copending U.S. Patent Application No. 11/688,001 ("the '001 application"; Atty. Ref. No. PC25026F) in view of Beers et al. Claims 7, 9, 11, and 12 stand rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of Bryans et al., U.S. Patent No. 6,635,673 ("the '673 patent"; Atty Ref. No. PC17322) in view of Beers et al.

35 U.S.C. §103(a)

Reconsideration is respectfully requested of the rejection of claims 7, 9, 11, and 12 under §103(a) as being unpatentable over Bryans et al. in view of *Merck*.

Claim 7 is directed to a method for treating fibromyalgia in a mammal, the method comprising administering to said mammal a therapeutically effective amount for treating fibromyalgia of (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid or a pharmaceutically acceptable salt thereof.

The Office asserts that the claimed invention is obvious and unpatentable over Bryans et al. in view of Beers et al. Applicants respectfully disagree, and repeat their assertion that the Office has not set forth a *prima facie* showing that the claimed invention is obvious.

The Office notes that "*The Merck Manual* clearly teaches the presence of pain in patients suffering from fibromyalgia." Certainly the subject application is consistent with this statement (see, e.g., page 1, lines 6 and 7 of the subject application: "Fibromyalgia (FM) is a chronic syndrome characterized mainly by widespread pain, unrefreshing sleep, disturbed mood, and fatigue."). However, the Office goes on to state that "[s]uch a teaching clearly raises the reasonable expectation that employing a therapeutic directed to treating pain in a patient suffering from fibromyalgia would necessarily ameliorate the overall condition of fibromyalgia, absent factual evidence to the contrary, since pain is a symptom of fibromyalgia."

While it is true that pain may be a symptom of fibromyalgia, Applicants do not agree that Merck raises a reasonable expectation that treating a symptom (indeed, one of potentially many symptoms) of fibromyalgia "would necessarily ameliorate the overall condition of fibromyalgia." The Office has given no reason why this would be the case. As the subject application explains, one suffering from fibromyalgia experiences many symptoms and syndromes:

> Fibromyalgia (FM) is a chronic syndrome characterized mainly by widespread pain, unrefreshing sleep, disturbed mood, and fatigue. The main symptoms of fibromyalgia include pain, sleep, mood disturbances

> and fatigue. Syndromes commonly associated with fibromyalgia include irritable bowel syndrome, and migraine headaches, among others. Success of treating fibromyalgia with a single pharmacological agent has been characterized as modest and results of clinical trials have been characterized as disappointing. It is believed that based on current understanding of the mechanisms and pathways involved in fibromyalgia, multiple agents will be required, aimed at the major symptoms of pain, disturbed sleep, mood disturbances, and fatigue.

See page 1, lines 6-15. Treatment of the syndrome – fibromyalgia – therefore cannot be expected to occur merely by addressing one of the many symptoms or associated syndromes. That is, there is nothing in Merck to suggest that an agent useful for ameliorating pain would also, for example, address other symptoms such as unrefreshing sleep, disturbed mood, or fatigue.

This is supported, as Applicant has previously mentioned, by the disclosure in Merck that pain medication such as aspirin or other NSAIDs in full dosages have not generally been shown to be effective in treating fibromyalgia. Nothing in Merck would have suggested to one of ordinary skill in the art that an agent known to be useful for ameliorating pain would be necessarily be further useful for treating fibromyalgia. Thus, Applicants submit that claim 7 is patentable over Bryans and Merck.

Claim 9 is directed to a method for treating fibromyalgia and a concomitant disorder in a mammal, the method comprising administering to said mammal a therapeutically effective amount for treating fibromyalgia and a concomitant disorder of (3*S*,4*S*)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid or a pharmaceutically acceptable salt thereof. Claim 9 defines the concomitant disorder as being selected from migraine headaches, temporomandibular joint dysfunction, dysautonomia, endocrine dysfunction, dizziness, cold intolerance, chemical sensitivity, sicca symptoms, cognitive dysfunction, generalized anxiety disorder, premenstrual dysphoric dysthemia, irritable bowel syndrome, functional abdominal pain, neuropathic pain, and somatoform disorders, OCD, phobias, and PTSD. Claims 11 and 12 depend from claim 9 and further limit the concomitant disorder.

Neither Bryans, Merck, nor the combination of the two teach the use of (3*S*,4*S*)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid or a pharmaceutically acceptable salt thereof for the treatment of fibromyalgia and a concomitant disorder as defined in any of claims 9, 11, or 12, for the same reasons given above with respect to fibromyalgia alone. Furthermore, these references do not describe or even suggest the treatment of fibromyalgia and any concomitant disorder. A *prima facie* showing of obviousness requires, inter alia, that the cited references describe or suggest every element of the claimed invention. See MPEP 2143. The cited references do not teach or suggest every element of claims 9, 11, and 12, and thus the Office has not shown that these claims are *prima facie* obvious.

Obviousness-type double patenting

Reconsideration is respectfully requested of the provisional rejection of claims 7, 9, 11, and 12 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of the '824 application in view of *Merck*; of the provisional rejection of claims 7, 9, 11, and 12 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of the '389 application in view of *Merck*; of the provisional rejection of claims 7, 9, 11, and 12 on the grounds of nonstatutory

obviousness-type double patenting as being unpatentable over claim 21 of the '001 application in view of *Merck*; and of the rejection of claims 7, 9, 11, and 12 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of the '673 patent in view of *Merck*. Applicants submit herewith a terminal disclaimer in connection with this rejection.

Applicants submit that these provisional and non-provisional rejections are improper. The doctrine of nonstatutory obviousness-type double patenting requires that one or more claims in the subject patent application is not patentably distinct from the subject matter claimed in a commonly owned patent (or patent application, in the case of a provisional rejection under this doctrine). The purpose of a rejection under this doctrine is "to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent." See MPEP 804(II)(B). The specification of the commonly owned patent or patent application may be considered, in certain circumstances, but it is improper to combine the teachings of the commonly owned patent or patent application with another reference, as has been done here. Thus, Applicants respectfully request that these provisional rejections, and the non-provisional rejection, be withdrawn.

Conclusion

For the foregoing reasons, the Applicants submit that the present invention is now in condition for allowance. Allowance of all pending claims is respectfully solicited.

Respectfully submitted,

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